



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,506	09/20/2006	Osvaldo Abreu	901-001-034	1385

86012 7590 12/02/2011  
VLP Law Group LLP  
555 Bryant Street  
Suite 820  
Palo Alto, CA 94301

EXAMINER
----------

VU, JAKE MINH

ART UNIT	PAPER NUMBER
----------	--------------

1618

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/02/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@vlplawgroup.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,506	<b>Applicant(s)</b> ABREU, OSVALDO	
	<b>Examiner</b> JAKE VU	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-8, 10-22, 24-48 and 50-78 is/are pending in the application.
- 5a) Of the above claim(s) 1-8, 10-22, 24-39 and 57-71 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 40-48, 50-56 and 72-77 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Election Requirement Response filed on 09/28/2011; Amendment filed on 02/17/2011; and Information Disclosure Statement filed on 10/28/2011.

- Claims 1-8, 10-22, 24-27, 31, 34, 40-41, 43-48, 50-56 have been amended.
- Claims 72-78 have been added.
- Claims 9, 23, 49 have been cancelled.
- Claims 1-8, 10-22, 24-48, 50-78 are pending in the instant application.
- Claims 1-8, 10-22, 24-39 and 57-71 have been previously withdrawn from further consideration; claim 78 is drawn to nonelected specie and is withdrawn consideration.

### ***Election/Restrictions***

Applicant's election without traverse of "activated charcoal" in the reply filed on 09/28/2011 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-48, 50-51, 54-56, 72-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

Art Unit: 1618

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the surface area when measured by BET.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. In this instance, Applicant failed to disclose species that are less than 100m<sup>2</sup>/g, greater than 100 m<sup>2</sup>/g or greater than 500 m<sup>2</sup>/g. Microcrystalline cellulose (see [0065]) is an example in the specification that can be used as an adsorbent, but Applicant is unable to find the surface area by BET. (See the reply filed on 02/17/2011, page 19, wherein Applicant was unable to find the BET surface area for microcrystalline cellulose).

Art Unit: 1618

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 1618

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40, 52-53 rejected under 35 U.S.C. 102(b) as being anticipated by CHURCH (US 6,353,145) **are withdrawn** in view of Applicant's Amendment.

Claims 40-51, 54-56 rejected under 35 U.S.C. 102(a,e) as being anticipated by OSHLACK et al (US 2003/0143269; herein after "OSHLACK1") **are withdrawn** in view of Applicant's Amendment.

However, upon further consideration of Applicant's Amendment, a new ground(s) of rejection is made as discussed below.

Claims 40-41, 50-51, 54-55, 72, 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by ZENZ et al (DE 4325465; see IDS filed on 12/24/2007) as evidence by WIKIPEDIA ([http://en.wikipedia.org/wiki/Silica\\_gel](http://en.wikipedia.org/wiki/Silica_gel)).

Applicant's claims are directed to an oral dosage composition comprising of: an active agent; a water-insoluble activated adsorbent which exhibit a surface area greater than 100m<sup>2</sup>/g; and an adverse agent, wherein a majority of the adverse agent is adsorbed onto the adsorbent.

ZENZ teaches an oral dosage composition comprised of: an active agent, such as naloxone; a water-insoluble activated adsorbent which exhibit a surface area greater than 100m<sup>2</sup>/g, such as silica gel; and an adverse agent, such as morphine, wherein the

Art Unit: 1618

adverse agent is adsorbed onto the adsorbent (see Example 9). Additional disclosure includes: emulsifying agent can be added (see Example 9) or other excipients, such as talc (see top of page 6), which is hydrophobic; tablets or capsules (see bottom of pg. 6).

WIKIPEDIA teaches that silica gel is porous, have a surface area of about 800m<sup>2</sup>/g, and is not biodegrade in water, which reads on water-insoluble.

Note, ZENZ inherently meets release rate limitation, since the release rate is an inherent property of the composition, wherein ZENZ's composition has all the ingredients as claimed by Applicant.

Claims 40-43, 50-56, 72-77 are rejected under 35 U.S.C. 102(b) as being anticipated by WELCH et al (US 3,642,986).

WELCH teaches an oral dosage composition comprised of: an active agent, such as calcium (see col. 2, line 61); a water-insoluble activated adsorbent which exhibit a surface area greater than 1000m<sup>2</sup>/g, such as activated charcoal (see col. 2, line 57); and an adverse agent, such as aspirin, wherein the adverse agent is adsorbed onto the adsorbent by thoroughly mixing (see col. 2, line 62-63). Additional disclosures include: tablet and capsules (see col. 2, line 10-11); sterate (see col. 2, line 61) which is a fatty acid and is composed of stearic acid; granules (see col. 2, line 70), which reads on particles;

***Allowable Subject Matter***

Independent claim 40 would be allowable if the limitations of claims 44 and 52 are amended into claim 40.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618